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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/658,515

09/09/2003

Mark A. Reiley

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1785

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7590

02/25/2009

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EXAMINER

PRONE, CHRISTOPHER D

ART UNIT

PAPER NUMBER

3738

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/658,515	<b>Applicant(s)</b> REILEY, MARK A.	
	<b>Examiner</b> CHRISTOPHER D. PRONE	<b>Art Unit</b> 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 October 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 19-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> .                                  | 6) <input type="checkbox"/> Other: _____                          |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :10/6/08 4/25/08  
11/5/07 7/30/07.

## DETAILED ACTION

### *Information Disclosure Statement*

Applicant should note that the large number of references in the attached IDS have been considered by the examiner in the same manner as other documents in Office search files are considered by the examiner while conducting a search of the prior art in a proper field of search. See MPEP 609.05(b). **Applicant is requested to point out any particular references in the IDS which they believe may be of particular relevance to the instant claimed invention in response to this office action.**

### *Claim Rejections - 35 USC § 112*

Claims 2-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "adapted and configured" in the claims is a relative term which renders the claim indefinite. The term "adapted and configured" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. This language of the claims, absent recitation of structural features, relies solely on a functional use (i.e. to replace a certain anatomical feature). The elected invention is directed to figure 36 and description of the elected illustrated device is found on pages 22-25 of the specification. Claim 1 positively sets forth structural elements of

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a body and a facet joint structure. However, claim 2 and all subsequent claims fail to positively set forth structure that would function after the removal of at least some of the lamina and/or other anatomical portions of the spinal process from the vertebral body. It is not clear from the specification, what form of modifications and/or structures would be inherent in the device after removal of at least some of the lamina and/or other anatomical portions of the spinal process.

The same argument is applicable for the subject matter set forth in each of the dependent claims 2-18.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 17, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by any of Wall [4693722], Homsy, et al [4778472], Morgan [4917701] and Zang [5314486].

In each reference, the illustrated prosthesis includes a prosthesis body for fixation to an anatomical bone structure and an artificial joint structure carried by the prosthesis body. In each instance, the devices are capable of performing the function as broadly set forth in the claims. With respect to claims 18 and 19, each device is made from a medical material from the group of known materials as set forth in claim 19.

Claims 2-17 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over any of Wall [4633722], Homsy, et al [4778472], Morgan [4917701] and Zang [5314486].

. The term "adapted and configured" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. This language, absent structural features, relies solely on a functional use (i.e. to replace a certain anatomical feature). The metes and bounds of the claims are not clearly present in the claims as it is not clear from the specification, what form of modification or structure would be inherent in the device after removal of at least some portion of the various anatomical structures as set forth in claims 2-17. It is not clear what structural distinction exists between each dependent claim as the elected embodiment of figure 36 illustrates just one prosthesis body and facet joint structure. Therefor it is not clear as to how each claim further defines the body and joint structure of claim 1 that would be reasonably clear to one of ordinary skill in the art.

### ***Response to Arguments***

Applicant's arguments filed 10/6/08 have been fully considered but they are not persuasive. The applicant argues that there is no requirement under 112 for a claim to contain a definition for any of its terms. A claim may not be specifically required to define a term with a definition, but it is required to particularly point out and distinctly

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claim the subject matter of the invention. When a claim is too broad and fails to define a degree or standard for asserting the requisite degree the examiner will look to structural language for support of the language. Claims 2-17 lack any additional structure or any specificity with respect to the intended use of the device. The language in these claims requires a device to be adapted to be used in a plurality of locations, wherein at least a portion of something is removed. This language is extremely broad and can be easily corrected by claiming more structural components to define how the device is adapted to be used in the desired manner. The applicant then argues that a skilled artisan would understand the scope of each claim and that there is no need for any additional structure. However this language describing the location is mainly language of intended use, which to be overcome only requires that the device is capable of performing that task. The claims require the device to be adapted and configured to replace a natural object, but there is no limitation on how or in what manner the device has to perform. So the claims leave it open to perform in any manner. If the applicant truly believes that the novel feature of his device is the use in all these locations under these conditions he is advised to file a continuation and pursue another application directed toward a method of using his device.

With respect to the art rejections the applicant argues that the art of record does not recite the same use. This is not convincing because all structural limitations are met and the applicant has failed to provide any factual reasoning why the prior art can't perform the intended use. The applicant then argues that each limitation was not addressed separately, but this was made clear in the 112 and under the art rejections.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **CHRISTOPHER D. PRONE** whose telephone number is (571)272-6085. The examiner can normally be reached on Monday through Fri 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christopher D Prone  
Examiner  
Art Unit 3738

/CDP/

/Corrine M McDermott/  
Supervisory Patent Examiner, Art Unit 3738